NNFA
National Nutritional Foods Association

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Division of Dockets Management
Food and Drug Administration
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To FDA Dockets Management	From David Seckman	
Co./Dept. Docket #: 2002N-0085	Co. NNFA	
Phone #	Phone # 202-223-0101	
Fax # 301-827-6870	Fax #	

Re: Docket No. 2002N-0085

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the April 29, 2004 Proposed Rule, "Public Health Security and Bioterrorism: Food Importation; Sampling Services and Private Laboratories Requirements," 69 Fed. Reg. 23460.

NNFA is a trade association representing the interests of more than 7,000 retailers, manufacturers, suppliers, and distributors of foods, dietary supplements, and other natural products throughout the United States. NNFA appreciates the opportunity to comment on the questions posed by FDA and applauds FDA's ongoing efforts to ensure the safety of the food supply.

NNFA supports FDA in its efforts to help ensure the integrity and scientific validity of data and results submitted to FDA concerning food imports involved in enforcement actions. At the same time, NNFA believes that many companies have always responded to enforcement actions legitimately. Therefore, NNFA takes the position that there is no reason to compel such companies to hire sampling services or private laboratories, nor is there a reason to bar such companies from contact with sampling services and/or private laboratories should they be hired.

FDA Should Not Compel Persons Subject to the Rule to Hire Sampling Services or Private Laboratories to Analyze Samples

In the preamble to the proposed rule, FDA appears to be of two minds as to whether those subject to the rule must hire independent sampling services.

The preamble asks for comments on whether FDA should require the use of independent sampling services, noting that such a requirement could be unfair to those who are able to take samples in a legitimate manner. 69 Fed. Reg. at 23463. However, subsequent to raising that question the preamble presents a section of the proposed rule titled "What Requirements Apply if You Collect Your Own Samples?" which applies "if you collect samples of your own imported food." Id.[1]

[1] There is an overall lack of clarity in the Proposed Rule. Sec. 59.1 on "Applicability" further confuses the issue of whether those subject to the own rule may sample their own food imports. That section states that the rule only applies to those who

> (1) Use a sampling service to collect samples of an imported food in connection with an FDA enforcement action; or
> (2) Use a private laboratory to collect, analyze, or test samples of an imported food in connection with an FDA enforcement action.

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Thus, it is unclear whether FDA has already resolved the issue of whether companies may sample imported food themselves. If this issue remains open for discussion, NNFA takes the position that companies should not be required to hire independent sampling services. Many food importers have been capably sampling their own products – without manipulating, altering or substituting samples in an illegitimate manner – and there is no reason to mandate that they stop doing so now.

Moreover, there is no basis for believing that independent sampling services will provide more careful or competent sampling services than importers can provide for themselves. In this proposed rule, FDA does not require that sampling services be accredited. Thus, there is no basis for ensuring that a sampling service acts in a more legitimate manner than a company sampling its own products.

In the preamble, FDA does not raise the question of whether food importers may carry out their own *analysis* of products sampled in response to an enforcement action. In fact, Sec. 59.105 is worded in such a way to suggest that even companies sampling their own products *must* hire private laboratories to do the analysis:

> if you collect your own imported food samples and *intend to have the samples tested or analyzed* and used in connection with an FDA enforcement action, you must comply with subpart C of this part. Proposed 21 C.F.R. §59.105.

Proposed Sec. 59.301 then goes on to outline the requirements for private laboratories analyzing collected samples without any provision for those who have the capacity to analyze their own samples.

NNFA takes the position that FDA should acknowledge that many companies have the capacity to perform their own testing – as well as sampling – and can do so with integrity. Because FDA has declined to require accreditation of private laboratories, there is again no basis to ensure that analyses by private laboratories are more accurate than those performed by the companies themselves.

Therefore, if the agency goes forward with this rule, NNFA suggests that FDA specify that companies may undertake their own analyses, and that if they do so they must comply with the testing and reporting guidelines specified in proposed Sec. 59.301.

FDA Should Not Bar Persons Subject to the Rule From Contact With Private Laboratories Testing or Analyzing Samples

In its discussion of Proposed Sec. 59.103, FDA states that "if you use a private laboratory to test or analyze samples of an imported food in connection with an FDA enforcement action," you must "not influence or interfere with the manner and process in which samples are tested and/or analyzed." FDA goes on to state: "For example, you should not tell the private laboratory how it should test the samples or which piece of equipment to use." 69 Fed. Reg. at 23462.

The section then goes on to state:

> (b) This part also applies to you if you are a sampling service or a private laboratory and you have been hired or retained to collect, analyze, or test an imported food in connection with an FDA enforcement action.

As written, the section implies that the rule does not apply to those who do not use either a sampling services or a private laboratory in connection with an enforcement action for imported food. However, as noted above, Proposed Sec. 59.105 then outlines the requirements that apply "if you collect your own samples." This section should also have a provision for companies that intend to do their own testing.

NNFA recognizes that FDA aims to ensure that tests and analyses are completed in an honest manner. Nonetheless, there is no reason to completely bar contact between those subject to the rule and private laboratories conducting the relevant testing. In many cases, companies may need to inform private laboratories about special characteristics of the imported food, which may make types of testing more appropriate or may warrant the use of certain equipment.

It is in the company's best interest to assure that proper sampling and testing is conducted when imported foods are subject to enforcement actions. Often the company itself has the greatest expertise regarding their particular products. Therefore, companies should have the right to interact with independent sampling services and private laboratories to ensure that appropriate sampling plans are used and suitable testing is conducted on foods held under enforcement actions.

In the interest of allowing testing to proceed in an efficient and productive manner, NNFA therefore urges FDA to withdraw this provision and instead to acknowledge that contact by a party subject to the rule with a private laboratory is permissible, as long as it does not interfere with the integrity of the tests or analyses.

Conclusion

NNFA appreciates the opportunity to comment on this rulemaking.

Respectfully submitted,

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